REPRODUCTIVE EQUITY NOW

December 4, 2023

The Honorable Xavier Becerra
Secretary, Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

The Honorable Julie Su
Acting Secretary, Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

The Honorable Janet L. Yellen
Secretary, Department of the Treasury
1500 Pennsylvania Ave, NW
Washington, DC 20220

*Via electronic submission*

**RE: Reproductive Equity Now Written Comment on Insurance Coverage of Over-the-Counter Preventative Services 1210-ZA31**

Dear Secretary Becerra, Acting Secretary Su, and Secretary Yellen:

We are writing in response to the Request for Information (RFI) 120-ZA31 issued by your agencies regarding insurance coverage of over-the-counter (OTC) preventative services and items. **Reproductive Equity Now strongly supports insurance coverage without a prescription and without cost-sharing of all OTC preventative products and services outlined in the RFI. Aligned with our expertise and central to our mission, we write to express our particular support for coverage of over-the-counter items related to reproductive care including folic acid for pregnancy care, breastfeeding supplies, and over-the-counter contraceptives.** We appreciate the opportunity to share our perspective and experience in support of the proposal and to provide suggestions for a successful implementation. Reproductive Equity Now is a grassroots organization focused on promoting equitable access to the full spectrum of reproductive health care for all people regardless of their race, ethnicity, income, zip code, gender, immigration status, ability, sexual orientation, or religion. Advancing reproductive justice and eliminating barriers to safe, legal abortion are central to our mission.

**Aligned with our commitment to health equity and reproductive justice, we urge the Administration to require insurance coverage for OTC contraception, folic acid during pregnancy, and breastfeeding supplies without a prescription requirement and without cost sharing.** This proposal is an opportunity to address the systemic inequities present in our health care system that create barriers to access, particularly for BIPOC communities, immigrants, young people, LGBTQ+ people, rural residents, and people with disabilities. As private insurers and Medicaid generally require a prescription to cover OTC products, making preventative services available without a prescription will remove a barrier to care and help increase access. Additionally, requiring insurance coverage of the proposed OTC preventative products and services with no cost-sharing will be key to ensuring meaningful access, without cost barriers, to these products for consumers.[1] Since 2020, Reproductive Equity Now has dedicated significant attention towards implementing several contraceptive access statutes in Massachusetts, and our experience has shone a light on the difficulty of helping consumers navigate their eligibility for state level insurance mandates. Our experience and knowledge in this implementation work informs our call for federal guidance requiring insurance coverage for OTC contraception, particularly given states' limited ability to govern self-insured, or ERISA, insurance plans.

The right to reproductive health care, including care for contraception, pregnancy, delivery, abortion, and miscarriage care, is not a real right unless every individual can safely access that care with autonomy and dignity. This includes meaningful access to contraception, folic acid to improve pregnancy outcomes, and post-pregnancy care such as breastfeeding supplies. As twenty-one states have moved to ban or severely restrict access to abortion in the wake of *Dobbs v. Jackson Women's Health Center*, we have seen the devastating impact of abortion bans on the full spectrum of reproductive health care, especially for marginalized communities.[2] In the wake of *Dobbs*, we are keenly aware of the need to make *all* reproductive health care as accessible as possible. In these comments, Reproductive Equity Now outlines why mandating insurance coverage of OTC contraception, folic acid, and breastfeeding supplies without a prescription and without cost-sharing is well construed not only to expand reproductive equity but specifically for populations that do not have access to a provider and who face cost barriers to accessing care. Finally, we provide implementation recommendations based on Reproductive Equity Now's experience with the, often problematic, implementation of the Massachusetts state law mandating insurance coverage of OTC contraception to ensure the goals of increased access are met.

## I. Oral contraception prescription requirements create barriers to access

The U.S. Food and Drug Administration's recent approval of Opill as the first over-the-counter oral contraception creates a promising opportunity to increase access to contraception across the

[1] Michelle Long et al., *Considerations for Covering Over-The-Counter Contraception*, KFF (Nov. 28, 2023), *available at* https://www.kff.org/policy-watch/considerations-covering-over-the-counter-contraception/?utm_campaign=KFF-2023-Womens-Health-Policy-WHP&utm_medium=email&_hsmi=284185506&_hsenc=p2ANqtz--kjAmawRoqNcOVQV5KiSmJW_DRF25jPWKAtgkuqNCm4Z7HXALZtHC9im6tjTQaE9KcaIkrJRs7ONN4Lz4IUpRWOL6jp1ryG_Ih5L29iY2fY8eP&log&utm_content=284185506&utm_source=hs_email.

[2] *See Tracking the States Where Abortion is Now Banned*, N.Y. TIMES (last updated Nov. 7, 2023), https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html.

nation by removing the barrier to obtaining a prescription at a time when states are moving to restrict access to reproductive health care such as abortion. As the RFI notes, most health insurance plans are required under the Affordable Care Act to cover contraception. While this has been instrumental in expanding access to contraception, under current guidance, most insurance plans require a prescription to cover OTC birth control. Coverage of OTC oral contraceptives without a prescription will expand reproductive equity by removing one of the key barriers to contraceptive access: obtaining a contraception prescription. There is strong evidence that prescription requirements for birth control pills create barriers to access, which over-the-counter access to oral contraceptives can eliminate. One-third of women who have tried to obtain or refill a prescription for birth control faced access barriers.[3] Access barriers include clinicians requiring a clinic visit, examination, or Pap smear as a prerequisite to obtaining a prescription for contraception, despite these preconditions being medically unnecessary.[4] The American College of Obstetricians and Gynecologists (ACOG) similarly states that pelvic and breast examinations, cervical cancer screening, and sexually transmitted infection screenings are not required before initiating hormonal contraception, and should not be used as reasons to deny access to contraceptive care.[5] Similarly, the U.S. Centers for Disease Control (CDC) guidance on birth control also indicates that most women do not need a physical examination before starting a method of contraception.[6] Research indicates that OTC oral contraceptives could increase the use of contraception and reduce the risk of unintended pregnancy, critical in the post-*Roe* era.[7]

Making oral contraception available over the counter without a prescription will address barriers present due to systemic discrimination in health care. Women, especially women of color, are more likely to suffer discrimination, abuse, and stigma in health care which may impact their access to care available with only a prescription. For example, thirty-three percent of Indigenous women, twenty-five percent of Latinx women, and twenty-three percent of Black women report mistreatment in health care at large.[8] In terms of access to contraception, women report similar systemic barriers.[9] For instance, a recent study found that forty-five percent of respondents

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[3] Kate Grindlay & Daniel Grossman, *Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy*, 25 J. Women's Health 249, 252 (March 2016), *available at* https://pubmed.ncbi.nlm.nih.gov/26666711/.
[4] Jillian Henderson et. al, *Pelvic Examinations and Access to Oral Hormonal Contraception*, 116 J. Obstetrics & Gynecology 1257 (Dec. 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3745305/.
[5] Am. Coll. of Obstetricians & Gynecologists, Comm. on Gynecologic Practice Op., Committee Opinion: Over-the-Counter Access to Hormonal Contraception (2012; replaced 2019), *available at* https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception.
[6] Loretta Gavin et al., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, 63 Morbidity and Mortality Wkly Rep. 1 (April 25, 2014), *available at* https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm?s_cid=rr6304a1_w.
[7] Hélène Guillard et al., *Modeling the potential benefit of an over-the-counter progestin-only pill in preventing unintended pregnancies in the U.S.*, 177 Contraception: Int'l Reproductive Health J. 7 (Jan. 2023), https://www.contraceptionjournal.org/article/S0010-7824(22)00397-3/fulltext.
[8] Saraswathi Vedam et al., *The Giving Voice to Mothers study: inequity and mistreatment during pregnancy and childbirth in the United States*, 16 Reproductive Health J. 77 (June 2019), *available at* https://reproductive-health-journal.biomedcentral.com/articles/10.1186/s12978-019-0729-2.
[9] *Id.*

reported experiencing at least one barrier to accessing contraception in the past year.[10] Those who were younger, identified as BIPOC, or who had lower levels of education were more likely to have experienced a challenge to access contraception.[11] Systemic discrimination related to sexual orientation and gender identity also poses a barrier to contraception access. Research indicates that lesbian and bisexual women have significantly lower odds of receiving contraception compared with heterosexual women.[12] Similarly, transgender individuals, particularly transgender men, face barriers to contraceptive care as they may anticipate being misgendered by clinicians, fear having their transgender status revealed, or feel uncomfortable and potentially unsafe in a clinical setting populated with primarily cisgender women patients.[13] Aligned with these systemic barriers, research indicates that trans masculine people are prescribed fewer oral contraceptives than cisgender women.[14] The need for a prescription has the potential to exacerbate this stigma, increase discrimination and mistreatment experienced in the health care system, and cause people to not seek care involving a prescription.

Expanding access to contraception without a prescription offers an opportunity to connect young people to care who may face difficulty navigating the health care system. According to a 2022 national study conducted by Advocates for Youth, barriers to accessing a prescription can be daunting, particularly for low-income and other marginalized teens: fifty-five percent reported facing at least one barrier to accessing prescription birth control pills that prevented them from obtaining it, thirty-six percent of respondents reported they lacked the time to schedule or attend an appointment with a clinician to obtain a birth control prescription, and nearly one-third of all respondents indicated that they did not have a regular health care provider.[15] Notably, of the respondents who were prevented from accessing prescription birth control pills, fifty-eight percent had pregnancy scares and twenty percent had unintended pregnancies.[16]

Requiring coverage for OTC oral contraception without a prescription is an opportunity to remove barriers for rural people and those who live in contraceptive deserts.[17] For example, nineteen

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[10] Katherine Key et al., *Challenges accessing contraceptive care and interest in over-the-counter oral contraceptive pill use among Black, Indigenous, and people of color: An online cross-sectional survey*, 120 CONTRACEPTION: INT'L REPRODUCTIVE HEALTH J. 109950 (April 2023), *available at* https://www.contraceptionjournal.org/article/S0010-7824(23)00003-3/fulltext.
[11] *Id.*
[12] Madina Agénor et al., *Contraceptive Care Disparities Among Sexual Orientation Identity and Racial/Ethnic Subgroups of U.S. Women: A National Probability Sample Study*, 30 J. WOMEN'S HEALTH 1406 (Oct. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8590146/.
[13] A. Francis et al., *Contraceptive challenges and the transgender individual*, 4 WOMEN'S MIDLIFE HEALTH J. 12 (2018), https://womensmidlifehealthjournal.biomedcentral.com/articles/10.1186/s40695-018-0042-1#citeas.
[14] Halley P. Crissman et al., *Leveraging Administrative Claims to Understand Disparities in Gender Minority Health: Contraceptive Use Patterns Among Transgender and Nonbinary People*, 9 LGBT HEALTH 186 (April 2022), *available at* https://www.liebertpub.com/doi/10.1089/lgbt.2021.0303.
[15] CLAUDIA HUI ET AL., ADVOCATES FOR YOUTH, BEHIND THE COUNTER: FINDINGS FROM THE 2022 ORAL CONTRACEPTIVES ACCESS STUDY (Sept. 26, 2022), *available at* https://www.google.com/url?q=https://www.advocatesforyouth.org/wp-content/uploads/2022/09/BehindTheCounter-OralContraceptivesAccessReport-2022-1.pdf&sa=D&source=docs&ust=1699037557140445&usg=AOvVaw31k96A64u3wvM_-CGzG9Gl.
[16] *Id.*
[17] Contraceptive deserts are a type of access desert, defined by Power to Decide as "counties where the number of health centers offering the full range of methods is not enough to meet the needs of the county's number of women

million women in the United States live in a contraceptive desert where they lack meaningful access to contraceptive methods, and over one million of these women live in a county without a health center offering the full range of contraceptive methods, with some women reporting traveling hundreds of miles to obtain a prescription for contraception.[18] Traveling long distances to obtain a prescription for oral contraception may prove impossible for individuals who do not have access to transportation, who must arrange child care, or who are not able to obtain time off of work.

## II. Cost creates barriers to access to contraception

Out-of-pocket cost is a primary barrier to accessing health care services in general, including contraception. As previously noted, while prescription contraception is required to be covered without cost-sharing under the ACA, the current federal policy does not apply to OTC contraception. As OTC oral contraception becomes available, it is crucial not to shift the cost burden from health care systems and insurance to individuals. No-cost insurance coverage of over-the-counter oral contraceptives removes cost barriers, especially for groups that face higher access barriers such as young people and people with low incomes. Several states have enacted laws requiring state-regulated private health plans to cover certain OTC contraception (such as emergency contraception and condoms) without a prescription and without patient-cost sharing, though these important strides do not apply to the nearly two-thirds of workers with employer-sponsored insurance that is not subject to these mandates.[19] Several states have also moved to use state-only funds to provide coverage for certain OTC contraceptives without a prescription for Medicaid beneficiaries.[20] Requiring no cost sharing for OTC contraceptives, similar to the ACA requirements, will address this patchwork coverage for patients across the nation by removing the significant barrier of cost. A uniform national approach will not only remove the cost barrier for people in all states, but will also improve implementation by avoiding patchwork policies across states, making it easier to educate consumers, providers, pharmacies, and other stakeholders about the increased coverage.

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eligible for publicly funded contraception, defined as at least one health center for every 1,000 women in need of publicly funded contraception." *Contraceptive Deserts*, POWER TO DECIDE , https://powertodecide.org/what-we-do/contraceptive-deserts (last visited Dec. 1, 2023).

[18] *Id.*

[19] As of August 2023, six states mandate insurance coverage for OTC without a prescription and without cost-sharing. State health insurance coverage only applies to one-third of most insurance plans as they typically apply to individual health insurance plans, public employer health insurance plans, and fully-insured plans offered by private employers. Conversely, nearly two-thirds of workers recieve employer-sponsored insurance, which are not typically subject to state health insurance requirements. *See State Private Insurance Coverage Requirements for OTC Contraception Without a Prescription*, KFF (last updated Aug. 2023), https://www.kff.org/other/state-indicator/state-private-insurance-coverage-requirements-for-otc-contraception-without-a-prescription/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[20] *State Medicaid Insurance Coverage Requirements for OTC Contraception Without a Prescription*, KFF (last updated Aug. 2023), https://www.kff.org/other/state-indicator/state-medicaid-coverage-of-otc-contraception-without-a-prescription/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

While some states have moved to cover OTC contraceptives without cost-sharing, research indicates that cost concerns are a persistent barrier to patient access. A recent study found that a large population of women would likely use OTC oral contraception with no or low out-of-pocket costs.[21] This study concluded that a low retail price and insurance coverage are crucial to providing equitable access to OTC oral contraceptives for low-income populations which would reduce barriers to contraceptive access and potentially decrease unintended pregnancy.[22] Similarly, another study assessing interest in the continued use of OTC contraceptives found cost barriers including participants being unable or unwilling to pay out of pocket for an OTC oral contraception compared to prescription oral contraception (even if they wanted to continue with the OTC contraceptives).[23]

## III. Access barriers to folic acid during pregnancy and breastfeeding supplies

While folic acid supplements and breastfeeding supplies are available over the counter without a prescription, under current federal guidance, a prescription is required to obtain insurance coverage of these OTC items. Patients face similar barriers in obtaining a prescription for folic acid or breastfeeding supplies as patients face in obtaining a contraception prescription, including systemic discrimination and lack of access to a provider discussed previously.

The benefits of folic acid during pregnancy are well-documented [24] and folic acid is both covered by insurance with a prescription after the enactment of the ACA and widely available over the counter without a prescription. Alarmingly, despite the implementation of the ACA which provided insurance coverage for prescription folic acid, significant racial and ethnic disparities exist between Black and Hispanic women and non-Hispanic white women.[25] Research indicates that lack of access is a major contributing factor to racial disparities. Chief among access barriers is out-of-pocket costs for OTC folic acid if patients are unable to obtain a prescription from their provider.[26]

Access to breastfeeding supplies with no cost sharing is one of many barriers to successful breastfeeding. While the benefits of breastfeeding are well-documented in reducing many different health risks for mothers and children, many barriers remain including lack of knowledge,

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[21] Alexandra Wollum et al., *Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women*, 30 Women's Health Issues 153 (May 2020), *available at* https://www.whijournal.com/article/S1049-3867(20)30003-7/fulltext.
[22] *Id.*
[23] Kate Grindlay et al., *Interest in Continued Use After Participation in a Study of Over-the-Counter Progestin-Only Pills in the United States*, 3 Women's Health Reports 904 (Dec. 2022), https://www.liebertpub.com/doi/10.1089/whr.2022.0056.
[24] As noted in the RFI, folic acid supplementsare recommended with an "A" rating to prevent neural tube defects for all persons planning to become pregnant or who could become pregnant. *See* U.S. Preventative Services Task Force, Final Recommendation Statement: Folic Acid Supplementation to Prevent Neural Tube Defects: Preventative Medication *e* (Aug. 1 2023), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/folic-acid-for-the-prevention-of-neural-tube-defects-preventive-medication.
[25] Kelvin Gibson, *Racial Disparities in Periconceptual Folic Acid Levels* (2020) (Ph.D. dissertation, Walden University), *available at* https://scholarworks.waldenu.edu/dissertations/9565.
[26] *Id.*

social norms, poor social or familial support, employment and childcare barriers, and lactation problems.[27] Significant racial and ethnic disparities exist in the United States in both the rates of initial breastfeeding and duration of breastfeeding, exacerbated by socioeconomic status.[28] Addressing these numerous barriers is outside the scope of this RFI, though requiring OTC coverage of breastfeeding supplies without a prescription is a positive step forward in removing the barrier of access to a prescription and cost. Out-of-pocket costs associated with breastfeeding are a barrier for many parents.[29]

## IV. Implementation Considerations

Based on our experience of implementation across New England, and specifically with implementation of the 2017 Massachusetts Contraceptive ACCESS Law[30], we offer the following recommendations on 1210-ZA31 to ensure successful implementation so that people across the United States may meaningfully access OTC oral contraceptives, folic acid, and breastfeeding supplies:

1. Issue guidance requiring insurers to cover the OTC contraception, folic acid, and breastfeeding supplies without age restrictions to ensure young people have access without parental consent. This guidance should include specific coding information to ensure that pharmacists and insurers can communicate clearly about insurance coverage of OTC contraception, folic acid, and breastfeeding supplies.
2. Promulgate regulations that include mandatory reporting by providers, pharmacists, and insurers on the number of OTC services and items accessed to track consumer use of the newly covered products and provide data for spotting any trends or issues in OTC coverage without prescription and without cost sharing.
3. Administrative guidance to stakeholders such as pharmacists, trade associations, and insurers will be critical for successful implementation. We recommend that pharmacists in particular receive guidance and training on processing OTC claims.

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[27] Office of the U.S. Surgeon General, The Surgeon General's Call to Action to Support Breastfeeding: Barriers to Breastfeeding (2011), *available at* https://www.ncbi.nlm.nih.gov/books/NBK52688/.

[28] Stephanie M. Quintero et al., *Race/ethnicity-specific associations between breastfeeding information source and breastfeeding rates among U.S. women*, 23 BMC Public Health 520 (March 17, 2023), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-15447-8#:~:text=Despite%20the%20known%20benefits%20of,Native%20people%20.

[29] Am. Coll. of Obstetricians & Gynecologists, Comm. on Gynecologic Practice Op., Committee Opinion: Barriers to Breastfeeding: Supporting Initiation and Continuation of Breastfeeding (Aug. 2013; replaced Feb. 2021), *available at* https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/02/barriers-to-breastfeeding-supporting-initiation-and-continuation-of-breastfeeding.

[30] *An Act Relative to Advancing Contraceptive Coverage and Economic Security in our State* ("ACCESS"), signed into law in November 2017, requires fully-insured Massachusetts health care plans to cover at least one contraceptive drug, device, or other product within each FDA-approved contraceptive method category with no deductible, copayment, or coinsurance. Additionally, this law allows consumers to access up to a 12-month supply of a patient's prescribed contraception at once, after an initial three-month supply is prescribed. There are additional provisions establishing no cost-sharing for over-the-counter emergency contraception purchased with a prescription or pursuant to a standing order. Mass. Gen. Laws ch. 32A, § 28.

4. Issue guidance to protect confidential health care information in health insurance documentation for dependents on an insurance policy, such as explanation of services and summary of payment forms. Without protecting information related to reproductive health care, young patients or patients experiencing domestic violence may opt not to use the insurance coverage if they fear a parent or partner will find the service listed in an insurance summary of payment or explanation of services.
5. Allocate funding for a public education campaign to educate patients about the availability of insurance coverage of preventive services without a prescription and without cost-sharing. Public education is key to ensuring meaningful access to preventative services and products included in the RFI. We may look to lessons learned from contraceptive coverage under the ACA. While the ACA has required insurance contraceptive coverage for over a decade, some people still pay out of pocket for contraceptives. For example, four in ten women of reproductive age do not know that most insurance plans are required to pay the full cost of birth control.[31] It will be important for public education to be provided in various languages and in a culturally competent manner to best reach communities facing access barriers.
6. Include requirements for coverage at the point of sale at all pharmacies to ensure no out-of-pocket costs are incurred by consumers. If consumers are alternatively required to pay for the OTC product at the point of purchase and later submit a claim for insurance reimbursement, barriers to access will remain. For instance, consumers may lack the funds to pay for products up-front and therefore still lack meaningful access to preventive supplies, or consumers may not receive reimbursement for out-of-pocket costs if they do not properly submit a reimbursement claim.

The work to advance reproductive health equity is broad and we thank you for the opportunity to provide information to expand access to reproductive-related care without a prescription and without cost sharing.

Sincerely,

Rebecca Hart Holder
President
Reproductive Equity Now

[31] Brittni Frederiksen et al., *Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage*, KFF (Nov. 3, 2022), https://www.kff.org/womens-health-policy/report/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage/#:~:text=Cost%20can%20be%20a%20barrier,a%20barrier%20to%20continued%20use.